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EG&G ROCKY FLATS

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ROCKY FLATS PLANT, P O BOX 464, GOLDEN, COLORADO 80402-0464 • (303) 966-7000

December 20, 1993

93-RF-14816

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Martin H McBride
Acting Assistant Manager for
Environmental Restoration
DOE, RFO

FINAL DATA VALIDATION PLAN, REVISION 2 - SGS-636-93

Attached please find Revision 2 of the Data Validation Plan for Environmental Management This revision incorporates comments from the Environmental Protection Agency, the Colorado Department of Health, and the Operable Unit Managers at EG&G Rocky Flats, Inc

The Sample Management Office is planning June 1, 1994 as the date of implementation This date is planned due to the following prerequisites

- Prior to implementation, three Standard Operating Procedures (SOPs) are required to administer the Plan "Graded Validation", "Contract Compliance Screening", and, "Performance Evaluation and Trending of Contracted Laboratories"
- The data validation contract will require modification due to the graded validation plan Prior to modification of this contract, two SOPs must be completed "Graded Validation" and "Contract Compliance Screening"

The Sample Management Office anticipates a three month time period for preparation, review, and approval of the three SOPs An additional two to three months will be required for modification of the validation subcontract These time frames are based on our experience with these processes at Rocky Flats

If you have any questions, please contact K S Schoendaller on 303-966-8630

S G Stiger
Associate General Manager
Environmental Restoration Management

KSS apt

Orig and 1 cc - M H McBride

Attachment
As Stated

cc
N I Castaneda - DOE, RFO
A H Pauole - " "
R J Schassburger - " "
M N Silverman - " "

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ENVIRONMENTAL MANAGEMENT
ENVIRONMENTAL RESTORATION SAMPLE MANAGEMENT OFFICE
DATA VALIDATION PLAN

1 INTRODUCTION

This plan identifies required subcontractor support for validation of radiochemical, organic, inorganic, and water quality data This plan utilizes the three levels of inspection as discussed in F C Garner's report entitled "A Comprehensive Scheme for Auditing Contract Laboratory Data" Garner adapted the Department of Defense's Military Standard "Sampling Procedures and Tables for Inspection by Attributes (also known as MIL-STD-105D) to laboratory data Additionally, a draft validation plan was prepared by Dr J Dick in July, 1992 This Environmental Restoration Sample Management Office final validation plan may contain paragraphs and checklists taken verbatim from these three documents None of these three documents included radiochemistry, however, radiochemistry is included in this validation plan

The data to be validated by the subcontractor will be generated from the analysis of environmental samples collected as part of the ongoing environmental management activities at the Rocky Flats Plant (RFP) The plan, and any procedures developed from this plan, shall specifically support the activities of the EG&G Rocky Flats, Inc Environmental Management Program The Analytical Program Chemists in the Environmental Restoration Management (ERM) Sample Management Office (SMO) are responsible for ERM/SMO data validation activities

Data validation is defined as a systematic review of analytical data from the analysis of environmental samples and their associated quality control samples The PARCC parameters (precision, accuracy, representativeness, completeness and comparability) are used as indicators of data quality A data validation process examines, but may not be limited to, the following areas

- Evaluation of data completeness
- Verification of instrument calibration
- Measurement of laboratory precision using duplicates
- Measurement of laboratory accuracy using spikes
- Examination of blanks for contamination
- Assessment of adherence to method specifications and QC limits
- Evaluation of method performance in the sample matrix

A data validation program generally has four main objectives

- To ensure that the data is of sufficient quality to support decisions regarding each area of concern (As always, data usability is the responsibility of the appropriate EG&G Rocky Flats Program Manager)
- To descriptively evaluate contract laboratory data quality
- To identify laboratories which are consistently below a minimum acceptable quality level
- To identify analytical problems within the contract laboratories, facilitating immediate solutions

Much of the data collected by Environmental Management (EM) at RFP has been under variously worded constraints that "no data will be used unless it has been validated " The term "validation" has been subject to various interpretations. Until now, "validated" has been defined by EM as "100% validation using functional guidelines which contain specific criteria" The qualifiers "valid", "acceptable", and "rejected" have been assigned to each analyte for each analytical method for each sample, as well as to the overall analysis

This plan defines validation as "graded validation" "belonging to a lot which has been inspected at a specified level and found to meet the acceptance criteria"

2 ACRONYMS

CCS	Contract Compliance Screening
EM	Environmental Management
EPA	Environmental Protection Agency
IAG	Interagency Agreement
OU	Operable Unit
QA	Quality Assurance
QC	Quality Control
SDG	Sample Delivery Group
SMO	Sample Management Office

3 SCOPE

The organic and inorganic data to be validated is typically presented to the subcontractor in the format of an EPA Contract Laboratory Program (CLP) data package, each data package will contain all the data from an analytical sample delivery group (SDG) Radiochemical data will be presented to the validators in the format specified in the *General Radiochemistry and Routine Analytical Services Protocol (GRRASP) - Part B, Radioanalytical Services Protocol (RASP),* latest version.

The subcontractor's data validation standard operating procedures (SOPs) and the SMO's validation guidelines define the QC parameters to be reviewed, set the acceptance criteria for the review, and define the data qualifier flags to be applied to the analytical results All of these documents have been approved by the SMO Analytical Program Chemists

This plan prescribes a graded approach to data validation at the Rocky Flats Plant.

4 GRADED APPROACH PLAN

4 1 The following data is of such importance that it will continue to be validated as presently defined at the 100 percent level

- Data from newly contracted laboratories (for a validation period of six months)
- Data from each new method performed by a laboratory (for a validation period of three months)

- Data from laboratories readmitted to the program after resolution of technical or quality problems (for a validation period of three months)
- Data from highly sensitive projects, i e. boundary wells along Indiana

4 2 All Operable Unit (OU) analytical work, unless specifically identified to the regulatory agencies by the RFP Program Managers, will be validated at the appropriate percentages as identified below

4 3 Data packages will continue to be prepared for all projects This requirement is based upon the assumption that initially obtaining a complete package allows for validation at any time Informing laboratories at the end of every month as to which SDGs shall be inspected would require additional time for the laboratory to prepare the appropriate packages This would cause delays in validation and would impact IAG schedules. Also, it is extremely difficult (sometimes impossible), for laboratories to generate packages several weeks/months after analysis The cost of compiling these types of packages may increase our costs since the laboratories would charge appropriately for retrieving archived data

4 4 All data packages will be screened to ensure contract compliance, e g , the analytical method employed conformed to the chain-of-custody specification A contract compliance screening standard operating procedure is under preparation The validation subcontractor will perform the CCS and inform the appropriate Analytical Program Chemist in the SMO when laboratories are not complying with the contract

4 5 The laboratories shall deliver electronic data packages to the EG&G specification (non-delimited ASCII) along with whatever hard copy is necessary as defined in *GRRASP*

4 6 Samples from projects which do not require validation will be indicated with a "Z" designation This designation may also be used for data that have never been reviewed in any fashion, e g some historical data for which the documentation is not available This category could also apply to data for which only results are available and for which no raw data exist Projects which currently do not require validation are the National Pollutant Discharge Elimination System (NPDES) and samples collected from the decontamination pad (samples beginning with the prefix DW) However, validation of these type samples may occur whenever the Project Manager deems it necessary

4 7 The unit of product for inspection purposes shall be the Sample Delivery Group (SDG) Using the individual sample as the unit of inspection would be quite inefficient, as the QA/QC work is always associated with an SDG An SDG is defined as a batch of samples of a single matrix, generally but not necessarily from one sampling activity, received for one analysis type over a period of 14 days or less and not to exceed 20 samples When necessary to meet holding times, smaller SDGs are analyzed Each data package is identified by an SDG number This SDG number is a unique number and is assigned by the specific laboratory Both alpha and numeric characters are allowable

Inspections for radiochemistry will be performed on SDGs segregated by instrumentation or method alpha spectrometry, gamma spectrometry, liquid

scintillation, gross alpha/beta by gas proportional counting, radiometric strontium, cesium, and ^{228}Radium by gas proportional counting, and ^{226}Radium by radon emanation Therefore, for example, a "single SDG" from a radiochemical laboratory may contain as many as six sub-SDGs

4 8 **Validated is defined as "belonging to a lot which has been inspected and found to meet the acceptance criteria"** The current practice of assigning "V", "A", and "R" qualifiers for valid, acceptable, and rejected data, respectively, will be continued

4 9 **The "lot" is defined as "the output of an individual contract laboratory for one month"** The one month time period has been chosen instead of the quarter as MIL-STD, Garner, and Dick suggested At the end of every month, the SMO will randomly select "SDGs" based upon what was output that month by each laboratory The IAG mandates a 21-working day turnaround for validation activities If this plan were based on quarterly submissions, the IAG time frame would be violated since it is necessary to wait until the end of a quarter to randomly select SDGs for any given quarter This plan will allow an 84-working day turnaround for validated data from time of shipment to time of completion of validation

Also, defining lots in terms of Operating Units or sampling locations would not give as ready a check on individual laboratory performance

4 10 An individual batch, or SDG, may or may not have been actually inspected, but all batches of validated data must belong to a "lot" which has been sampled, and accepted or rejected Unvalidated data associated with a "lot" will be designated by the last digit of the year and the two-digit month in which the "lot" was validated

4 11 Validation will occur at three levels of inspection utilizing the validation guidelines currently in use by Environmental Management The three inspection levels are reduced, normal, and tightened Validation of sample delivery groups will occur at each level at the following percentages

- 25% at the reduced level
- 50% at the normal level
- 75% at the tightened level

4 12 The three levels of inspection (which lead to validation), as described in Garner are

Reduced Inspection Level - The level of inspection appropriate when observed and documented past performance indicates a laboratory is of exceptional quality This permits commitment of validation resources to laboratories of lesser quality.

Normal Inspection Level - The level of inspection appropriate at the start of inspection and for laboratories of acceptable but not exceptional quality

Tightened Inspection Level - The level of inspection appropriate when

observed past performance indicates a laboratory may not be producing data packages of acceptable quality

4 13 Normal inspection will be initiated for each laboratory at the start of inspection under this validation plan Tightened or reduced inspection will then be initiated after certain specific performances have been observed The switching criteria used to change from one level to another are

Normal to Tightened - Tightened inspection will be initiated upon rejection of any batch

Normal to Reduced - Reduced inspection will be initiated after three consecutive batches have been accepted Past performance of the laboratory will be considered when switching from normal level to reduced level

Reduced to Normal - Normal inspection will be initiated following reduced inspection whenever any major change occurs in the analytical method, instrumentation, or key analytical personnel

Reduced to Tightened - Tightened inspection will be initiated following reduced inspection upon rejection of any batch

Tightened to Normal - Normal inspection will be initiated following tightened inspection after three batches have been accepted

SDGs which are rejected shall trigger 100% validation of the data in the associated lot to determine which packages would also be rejected Additionally, tightened inspection will be initiated

4 14 MIL-STD-105D requires that all data packages to be actually inspected must be chosen at random This means that all SDGs at the same inspection level must be equally likely to be inspected It must be emphasized that the inspector must not preferentially choose SDGs which are more or less likely to have "defects" Appropriate computer software makes this requirement easily achievable

4 15 The inspection will entail an examination of the SDGs chosen for inspection in the same manner as has been previously employed for validation of each individual SDG In addition to the previously employed qualifiers, a running tally of performance indicators shall be kept

4 16 The validation procedure will entail examination of the randomly sampled SDGs Each validator has an identical checklist, and the examination method is uniform among validators Thus, each validator is equally likely to identify each type of "defect" as any other validator examining the same SDG

4 17 All identified "defects" should be corrected when practicable The laboratory should be required to supply missing data, or reanalyze the sample or control In addition to measuring laboratory performance, the quality of the data may be somewhat improved if corrective action is taken

4.18 Laboratories generating rejected lots should be informed of all problems, and should receive no more samples until the conditions leading to rejection of data are corrected

4 19 Data "defect" tallies will be used to derive control charts for each laboratory Degradation in performance should be observable in time to allow effective corrective action

5 IMPLEMENTATION

5 1 Implementation of this plan is scheduled for June 1, 1994

5 2 Standard Operating Procedures "Graded Validation", "Contract Compliance Screening", and, "Performance Evaluation and Trending of Contracted Laboratories" are under preparation